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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,613	03/03/2006	Michael Volland	BOEHMERF-0001	9710

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1653

NOTIFICATION DATE	DELIVERY MODE
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09/26/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/570,613	Applicant(s) VOLLAND ET AL.	
	Examiner SUSAN HANLEY	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-19 is/are pending in the application.
- 5a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-13 and 16-19 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/03/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-19 are pending.

Applicant's election of Group II, claims 1-14 and 16-19 with traverse is again acknowledged.

Claims 14 and 15 stand withdrawn.

Claims 1-13 and 16-19 are under examination.

IDS

In the IDS filed 3/3/2006, items 2-6 were lined through since they were not cited in the search report and the documents themselves were not provided.

In the remarks filed 6/16/2001, Applicant states that the references for the lined out citations have been provided with the exception of cite no. 6 which is equivalent to JP 63302929 and which was cited by the examiner. The references for citations 2-4 have been provided. Applicants states that "Cite No. 5 is equivalent to JP 03/109935" and provides an abstract from Thomson Innovation Record View for that document. This document is considered to be the reference for this citation. The full published application for JP 03/109935 has been translated and it has been applied as prior art (see below). Since Applicant has supplied the reference in the IDS, the instant action will be made FINAL based on the IDS submission which has now been fully provided by Applicant.

Claim Rejections - 35 USC § 103

Claims 1-10, 12, 13, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP403109935; English translation) in view of Heroufousse et al. (US 2004/0166215).

Suzuki et al. teach a process for making an emulsifier by reacting a phospholipid that is lecithin (instant claims 1 and 2) with a mixture of fats and oils (e.g., triglycerides) and a phospholipase A in a small amount of water. Glycerol is added with a lipase the reacts with the resultant reacted mixture. The phospholipid is a lecithin that can be from soybean from a genus of three lecithins. A genus of three sources of lecithins is a small genus from which the ordinary artisan can easily envisage the selection of phospholipid from soybean (instant claim 16). The oil can be of animal or plant origin (instant claim 3). The phospholipase A can be of animal or microbial origin (instant claim 7; all from p. 4; reference of page numbers refers to the translation). Suzuki et al. teach that the phospholipase A is allowed to act on a mixture of phospholipase with oils and fats (p. 2, under section (2); Scope of the claims). This disclosure is reasonably interpreted to mean that the phospholipase acts on all of the components of the mixture. It is noted that the transitional language of instant claim 1 is “comprising.” The term “comprising” is open language. Hence, the prior art components or steps (fats and the addition of glycerol and a lipase, respectively) can contain additional elements that are encompassed by, but not specifically named, by the claims.

The desirable ratio by weight of phospholipid to oils and fats is 4:6 to 8:2 (p. 5, fourth full paragraph). In terms of percentage, this is from 4 parts phospholipids to a

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total of 10 parts of phospholipids and oils and fats to 8 parts to 8 parts phospholipid to a total of 10 parts phospholipids and oils and fats or 40% to 80% phospholipids. 40% to 80% is a specie that anticipates the claimed range of 10 to 80% (instant claim 4).

Conversely the amount of triglycerides is from 20 to 60% which is a specie that anticipates the claimed range of from 20 to 90% (instant claim 5). although fats are include with the oils, fats are simply solid triglycerides that at to the total triglycerides.

The water content is from 0.1 to 1.0 parts by weight relative to 1 part (2nd full paragraph of p. 5). Said ratio is parts water to total parts which is 0.1/1.1 to $\frac{1}{2}$ which is 9.1 to 50% by weight. 9.1% is a specie that anticipates the claimed range of between 3 and 15% (instant claim 1). The generic disclosure suggests or motivates the specific value, 15%, which is the upper end of the claimed range. The values between 9.1 and 15% water are species within the prior art which suggest the same percentage as claimed.

The reaction time varies with the amount of enzyme added but it is roughly in the range from 30 min. to 60 hours (p. 6, fourth paragraph). 60 hours is a specie that anticipates the period beyond 2 hours. The generic disclosure suggests or motivates the specific value, 2 hours which is the lower end of the claimed range. The values between 2 and 60 hours are species within the prior art which suggest the same range of hours as claimed (instant claim 1). 10 hours is a specie that anticipates the range of 5 to 20 hours (instant claim 10). The generic disclosure suggests or motivates the specific value, 5 hours which is the lower end of the claimed range. The values between 10 and

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20 hours are species within the prior art which suggest the same range of hours as claimed.

The reaction temperature is preferably from 20 to 80 degrees C (top of p. 6) which meets the claimed range of instant claim 1.

Suzuki et al. do not teach the emulsifier is dried.

Heroufousse et al. teach that powdered emulsifiers are used in the cosmetics and pharmacy industries. Examples of emulsifiers are monodiglycerides (reasonably interpreted as mono- and di-glycerides). Emulsifiers are put into powder form by spray cooling, spray chilling, grinding, milling or any other method (sections [0003] to [0005]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to convert the emulsifier prepared by the method of Suzuki et al. to a powder. The ordinary artisan would have been motivated to do so because emulsifiers are commonly used as powders in the pharmaceutical and cosmetics industries. The ordinary artisan would have had a reasonable expectation that one could convert the emulsifier of Suzuki et al. into a powder since Heroufousse et al. teach several methods to do so.

The reference is silent regarding the characteristics of the mixture (instant claims 12 and 13) obtained after the phospholipase step but meets the claimed limitations wherein a mixture of phospholipid and triglycerides are reacted with a phospholipase which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe naturally includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

While the reference does not specifically teach the limitations that the reaction is carried out at a temperature between 35 and 60 degrees C (instant claim 6) or for between 40 and 50 degrees C (instant claim 9) for between 8 and 12 hours (instant claim 19) and the amount of lipase is between 0.05 and 10 mg/ml (instant claim 8), one of ordinary skill in the art would recognize the temperature and time of the reaction as well as the amount of enzyme used are result effective variables dependent on the desired degree of lipid conversion. This is motivation for someone of ordinary skill in the art to practice or test the parameter values widely to find those that are functional or optimal which then would be inclusive or cover that values as instantly claimed.

The claimed ranges for temperature and time are within the disclosed range. hence, the ordinary artisan would have been motivated to determine the optimum temperature and time within the ranges. Suzuki et al. teach the activity per mg (p. 5, last paragraph) . This is a starting point to optimize the concentration of the enzyme in the enzyme in the reaction mixture. Absent any teaching of criticality by the Applicant concerning the time and temperature of the reaction or the amount of enzyme utilized, it would be prima facie obvious that one of ordinary skill in the art would recognize these

limitations are result effective variable which can be met as a matter of routine optimization (MPEP § 2144.05 II).

Claims 1-10, 12, 13, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP403109935; English translation) in view of Heroufousse et al. (US 2004/0166215), as applied to claims 1-10, 12, 13, 16 and 18, in further view of Hattori et al. (US 5,378,623).

The combined disclosures by Suzuki et al. and Heroufousse et al. are discussed supra.

The combined disclosures do not teach that the microbial source of the phospholipase A is from *Aspergillus* (instant claim 17).

Hattori et al. disclose a phospholipase A1 from *Aspergillus* which is capable of hydrolyzing a phospholipid to produce a 2-acyl lysophospholipid (abstract).

Phospholipase A1 is a specie of phospholipase A. It is noted that the phospholipase is exhibits lipase activity from the preparations from examples 2 and 4 (Table 3 col. 20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the phospholipase A1 that exhibit lipase activity taught by Hattori et al. to carry out the transformation of phospholipids, fats and oils taught by Suzuki. The ordinary artisan would have been motivated to do so because Suzuki et al., teaches that phospholipases of a microbial origin can be utilized for the reaction. The ordinary artisan would have had a reasonable expectation that the phospholipase taught by Hattori et al. would be able to carry out the first part of the reaction taught by

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Suzuki because the phospholipase A1 of Hattori has phospholipase A activity as well as lipase activity.

Claims 1-12, 13, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP403109935; English translation) in view of Heroufousse et al. (US 2004/0166215), as applied to claims 1-10, 12, 13, 16 and 18, in further view of Grote et al. (6,162,623) and Hansen et al. (US 5,888,562).

The combined disclosures by Suzuki et al. and Heroufousse et al. are discussed supra.

The combined disclosures do not teach that the drying step occurs at a temperature between 60 and 80 degrees C (instant claim 11) in a vacuum (instant claim 18).

Grote et al. teach the preparation of an emulsifier by treatment of triglycerides with a lipase and that generally emulsifiers are dried in a vacuum by the gradual removal of water (col. 3, lines 44-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carrying out the drying step disclosed by the combined references by vacuum. The ordinary artisan would have been motivated to do so and would have had a reasonably expectation that one could do so because Grote et al. successfully accomplishes this this with a triglyceride-lipase-hydrolyzed emulsifier which is similar in composition to that of the emulsifier of the combined references.

Hansen et al. teach that water can be removed enzymatically treated compositions such as cocoa by gentle heating at 60 degrees C under vacuum (col. 10,

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lined 15-23). Hansen et al. is analogous prior art since the method pertains to the removal of water from an enzymatically treated substance. The temperature of 60 degrees C is a specie that anticipates the claimed range of 60 to 80 degrees c (instant claim 11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to remove water from the emulsion of the combined references by gentle heating under a vacuum. The ordinary artisan would have been motivated to do so because heating and vacuum drying would reasonably decrease the drying time of the emulsion since the employment of two methods that effect the same result would reasonably have an additive effect. The ordinary artisan would have had a reasonable expectation that one could remove water from the emulsion by vacuum and heating since the combination has been shown to remove water by the method of Hansen et al.

Applicant's submission of the reference for citation 6 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on 571-272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Primary Examiner, Art Unit 1653